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No. 06-179

In the Supreme Court of the United States

CHARLES R. RIEGEL, *et al.*,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts petitioners' state common law damages claims challenging the design, testing, manufacture, distribution, labeling, and marketing of Medtronic's Evergreen Dilatation Balloon Catheter, when that device was granted pre-market approval (PMA) by the Food and Drug Administration (FDA) and when each of petitioners' claims would impose requirements relating to the safety or effectiveness of the device that would be "different from" or "in addition to" the federal requirements embodied in the FDA's pre-market approval of the device.

RULE 29.6 STATEMENT

Respondent Medtronic, Inc. is a publicly traded corporation and has no corporate parent. No other publicly held company owns 10 percent or more of respondent's stock.

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BRIEF FOR THE RESPONDENT IN OPPOSITION

On at least five occasions in as many years, this Court has denied petitions for certiorari raising issues identical to those presented here. See *McMullen* v. *Medtronic, Inc.*, 126 S. Ct. 1464 (2006); *Knisley* v. *Medtronic, Inc.*, 126 S. Ct. 420 (2005); *Brooks* v. *Howmedica, Inc.*, 535 U.S. 1056 (2002); *Martin* v. *Medtronic, Inc.*, 534 U.S. 1078 (2002); *Kemp* v. *Medtronic, Inc.*, 534 U.S. 818 (2001). The grounds for denying certiorari, already ample when those prior petitions were reviewed, are even stronger today.

Contrary to petitioners' assertion (Pet. 14), the lower courts are *not* "deeply divided" regarding the application of *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). Quite the opposite. A clear and growing consensus has emerged that—consistent with this Court's teaching in *Lohr*—FDA premarket approval (PMA) of a medical device preempts conflicting state law claims arising from the design, manufacture, and labeling of such a device. Every court of appeals to have considered the issue in the past seven years has concluded, as did the Second Circuit below, that the FDA's vigorous PMA process establishes device-specific federal requirements that, under 21 U.S.C. § 360k(a), preempt state common law damages claims that would effectively create state requirements "different from" or "in addition to" the federal requirements.

Although there is some vestigial inconsistency in the lower courts' interpretations of *Lohr*, the remaining conflict is increasingly stale and likely to disappear even without this Court's intervention. The only cases to hold that state common law damages claims are never preempted by PMA approval were decided nearly a decade ago, shortly after this Court's decision in *Lohr*. Since then, this Court's subsequent decisions in *Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000), and *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), have given clear guidance on the proper

interpretation of *Lohr*. Moreover, the United States has since filed an *amicus curiae* brief in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004), setting forth the FDA's considered opinion that, under the relevant FDA regulation, approval of a medical device through the PMA process generally preempts state common law claims arising from the use of such a device. Given *Geier*, *Buckman*, and the government's *amicus* brief in *Horn*, the few lower courts that had initially misinterpreted *Lohr* are likely to revise their aberrant views without further action by this Court.

STATEMENT

A. The regulatory structure of the Medical Device Amendments.

In 1976, Congress enacted the Medical Device Amendments (MDA), 21 U.S.C. §§ 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, which vastly expanded the authority of the FDA to regulate medical devices. At the same time that it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. REP. No. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including in the MDA a "general prohibition on non-Federal regulation." *Id.* at 45. That general prohibition, which also serves to safeguard the uniformity of the federal regulatory scheme, broadly provides that no state may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable * * * to the device" under federal law. 21 U.S.C. § 360k(a).

This Court has twice considered the preemptive scope of the MDA—in *Lohr* and, more recently, in *Buckman*. In a fractured opinion, the *Lohr* Court held that the MDA's express preemption clause did not bar state law tort actions challenging the design, manufacture, or labeling of "Class

III" devices—*i.e.*, devices that either (1) are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or (2) "present[] a potential unreasonable risk of illness or injury," *id.* § 360c(a)(1)(C)(ii)—if those devices had been approved for sale through a simple "premarket notification" under the "510(k)" process as the "substantial[] equivalent" of a device in existence before the passage of the MDA. See *Lohr*, 518 U.S. at 492–494.

Explicitly differentiating the 510(k) notification process, at issue in *Lohr*, from the PMA process at issue here, the *Lohr* Court noted that "[t]he § 510(k) notification process is by no means comparable to the PMA process." 518 U.S. at 478–479. Thus, "[b]efore a new Class III device may be introduced to the market" via the far more exacting PMA process,

> the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. See 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance" [in the PMA process] is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.

Id. at 477 (citations omitted). The Court contrasted this "rigorous" review with the 20 hours typical for a 510(k) review. *Id.* at 479. Because the device at issue in *Lohr* had been marketed "without running the gauntlet of the PMA process," *id.* at 494, the *Lohr* Court never addressed the preemptive scope of the PMA process.

In finding 510(k) approval not preemptive, the *Lohr* Court laid out a basic framework for analyzing express preemption under the MDA. First, a majority of the Court held

that one must engage in a "careful comparison" of the details of the federal requirements applicable to the device and the state requirements that are arguably preempted. 518 U.S. at 500. Second, a majority of the Court specifically found that state common law tort actions seeking damages *could* impose "requirements" and thus be preempted. See *id.* at 504–505 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Finally, a majority of the Court found that only "specific" federal requirements could be preemptive, and only of "specific" state requirements. See *id.* at 500; *id.* at 506–507 (Breyer, J., concurring). Under this framework, the Court determined that approval through the 510(k) process—which "is focused on *equivalence*, not safety" (*id.* at 493 (emphasis in original) (internal quotation omitted)), and which does "not 'require'" a medical device "to take any particular form for any particular reason" (*ibid.*)—did not preempt the state law claims raised by the Lohrs.

Like *Lohr*, *Buckman* addressed preemption when a device had been approved through the 510(k) process. The plaintiffs in *Buckman* alleged that they were injured by a device manufacturer's "fraud on the FDA." But for fraudulent disclosures to the FDA, they claimed, the agency would not have approved marketing of a device and thus plaintiffs would not have been injured. The Court—noting that "although [*Lohr*] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim" (531 U.S. at 353)—found such claims to be impliedly preempted by the MDA. Fraud on a federal agency, the Court held, was not a matter historically of state concern, and "fraud-on-the-FDA claims would * * * cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Agency, will later be judged insufficient in state court." *Id.* at 351.

B. The Evergreen Balloon Dilatation Catheter was subject to extensive regulatory review prior to receiving FDA approval.

Both *Lohr* and *Buckman* stressed the "thorough review" (*Buckman*, 531 U.S. at 344; see also *Lohr*, 518 U.S. at 477) that Class III medical devices must undergo before obtaining approval from the FDA pursuant to the PMA process. Prior to receiving FDA approval, the Medtronic Evergreen Balloon Dilatation Catheter (Evergreen Balloon Catheter), a Class III device used for angioplasty on patients with coronary artery disease, underwent this thorough review.

To obtain FDA approval via the PMA process, a manufacturer such as Medtronic

> must submit a detailed PMA application that contains full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information.

Pet. App. 8a (citing 21 U.S.C. § 360e(c)). In addition, the manufacturer "must include data from clinical investigations to establish the safety and effectiveness of the device." *Ibid.* (citing 21 C.F.R. § 814.20(b)(6)(ii)). The FDA closely scrutinizes the PMA application. If it is not satisfied with the information provided, it can demand more information. See Pet. App. 9a (citing 21 U.S.C. § 360e(d)(3), 21 C.F.R. § 814.44(e)). The FDA may also refer the application to an outside advisory panel. See *ibid.* (citing 21 C.F.R. § 814.44). If the FDA decides that the device's design, manufacturing methods or labeling should be revised, the agency can require such revisions as a condition of approval. See *ibid.* (citing 21 C.F.R. § 814.44(e)). In any event, if the device is ultimately

approved, "the applicant is required to comply with the standards in the PMA approval order." *Ibid.* (citing 21 C.F.R. § 814.80).

If a manufacturer wishes to make any changes that might affect the safety or efficacy of a device after it has received PMA approval, the manufacturer must submit a PMA Supplement, which is then subject to renewed FDA scrutiny. The proposed changes may be made only if they receive FDA approval. Pet. App. 10a (citing 21 C.F.R. § 814.39(a)). A PMA Supplement is subject to the same standards of review as an initial PMA application. See 21 C.F.R. § 814.39(c) ("[a]ll procedures and actions that apply to an application under § 814.20 also apply to PMA supplements"); see also *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000) (noting that the "procedures applicable to a PMA Supplement are the same as those applicable to an original PMA").

In this case, Medtronic's initial submission to the FDA in connection with the Evergreen Balloon Catheter was made in June 1987, when Medtronic filed a PMA application for an antecedent catheter system. A109.[1] That application was granted the following year. *Ibid.* In March 1994, Medtronic submitted a PMA Supplement for the Evergreen Balloon Catheter. A112. As part of that supplemental application, Medtronic submitted "extensive information about the safety and effectiveness" of the device, all of which was "specific to the Evergreen Balloon Catheter." Pet. App. 65a. Thus, Medtronic provided the FDA with design details, clinical test data, proposed product labels, and a precise description of how the catheter would be produced. See *ibid.*; see also A422–A427. On August 30, 1994, the FDA approved Medtronic's application for the Evergreen Balloon Catheter. Pet. App. 3a. The conditions of approval provided that Medtronic was required to submit a PMA Supplement "[b]efore making

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[1] Citations to A___ are to the Appendix filed below.

any change affecting the safety or effectiveness of the device." A116.[2]

C. Petitioners' case in the lower courts.

1. Petitioners are Charles Riegel (Riegel) and his wife, Donna. In May 1996, Riegel, who suffers from coronary disease, underwent surgery intended to unclog his right coronary artery. After several unsuccessful attempts using other devices, Riegel's surgeon decided to perform angioplasty using an Evergreen Balloon Catheter. Pet. App. 4a, 76a; see also A106–A107.

During angioplasty, the catheter is inserted into the patient's artery and the balloon near its tip is then inflated to open the clogged vessel. Thereafter, the balloon is deflated and the device is removed. Pet. App. 3a.

The surgeon's decision to use the Evergreen Balloon Catheter on Riegel was directly contrary to the device's FDA-approved labeling. Pet. App. 38a–43a; *id.* at 90a. Prior to his surgery, Riegel was diagnosed as having a "diffusely diseased" and "heavily calcified" right coronary artery. Pet. App. 4a. The FDA-approved labeling specifically warned that use of the Evergreen Balloon Catheter "is contraindicated"—*i.e.*, is inappropriate—in patients having "diffuse or calcified stenoses." Pet. App. 83a. Because calcification is often associated with hard, sharp points within a clogged artery, it increases the likelihood that the balloon will burst when inflated. Pet. App. 82a; see also A237. Thus, Riegel was not an appropriate candidate for the Evergreen Balloon Catheter. Pet. App. 90a.

Even if Riegel had been a proper candidate for the Evergreen Balloon Catheter, the surgeon chose to use the device

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[2] Medtronic subsequently submitted three PMA Supplements in connection with proposed revisions to the design and labeling of the Evergreen Balloon Catheter. Two of those Supplements were approved by the FDA on April 27, 1995; the third was approved on April 18, 1996. See Pet. App. 3a; A45.

in a manner inconsistent with its labeling. The FDA-approved instructions for the device specifically warn that the "[b]alloon pressure should not exceed the Rated Burst Pressure." Pet. App. 83a. The specific model used on Riegel, the 3.0–20 mm Evergreen Balloon Catheter (Pet. App. 76a), has a Rated Burst Pressure of 8 atmospheres (atm). Pet. App. 84a. Despite this fact, which is clearly noted on the FDA-approved labeling, the surgeon inflated the balloon to 10 atm, or 25 percent higher than approved. Pet. App. 83a.

As a result, the balloon burst while inside Riegel's artery. Pet. App. 43a, 90a; see also A235–A241. As a consequence, Riegel had to undergo emergency bypass surgery. He recovered, although he asserts that he suffered lasting injuries. Pet. App. 4a.

2. Petitioners sued Medtronic. Riegel alleged that Medtronic was "negligent in the design, testing, inspection, manufacture, distribution, labeling, marketing, and sale" of the Evergreen Balloon Catheter, that Medtronic had breached express and implied warranties, and that Medtronic was strictly liable for Riegel's alleged injuries. Riegel's wife asserted a derivative claim alleging loss of consortium. Pet. App. 4a–5a; see also A17–A22.

Medtronic moved for summary judgment on the ground that all of petitioners' claims—other than the express warranty claim, which Medtronic moved to dismiss under Fed. R. Civ. P. 12(b)(6)—were preempted under 21 U.S.C. § 360k(a). In a decision issued on March 14, 2002, the district court granted Medtronic summary judgment on the strict liability and implied warranty claims and on each of the negligence claims other than negligent manufacturing, holding that those state-law claims were preempted under § 360k(a). Pet. App. 68a, 71a.

In factual findings that petitioners do not dispute, the district court found that, as part of the PMA process leading to FDA approval of the Evergreen Balloon Catheter, Medtronic had "submitted extensive information about the safety

and effectiveness" of the device. Pet. App. 65a. That information, all of which was "specific to the Evergreen Balloon Dilatation Catheter," included "test data, the results of clinical investigations and design information" as well as "full copies of proposed product labels." *Ibid.* The district court found that "[t]he Catheter's design was specifically approved by the FDA" and—having been determined by the agency "to provide reasonable assurances of safety"—"cannot be changed or modified without FDA approval." Pet. App. 67a. The court also found that the same was true of the device's manufacturing process and labeling, which were "approved by the FDA in their entirety." *Ibid.*

Because Medtronic "was prohibited from changing the FDA-approved design, labeling, or manufacturing methods without further FDA approval," Pet. App. 65a, the district court found that "[t]he FDA's approval under the PMA process imposes standards on the device manufacturer that are fixed and required." Pet. App. 66a. Accordingly, the district court concluded, "[o]nce the FDA approves these specific safety requirements for a device, those requirements constitute a specific federal requirement, as contemplated for preemption purposes under *Lohr*." *Ibid.*

Given the FDA's approval of the catheter's design, manufacturing method, and labeling, the district court further found that a jury verdict holding Medtronic liable for negligent design, improper manufacturing methods, inadequate labeling, or breach of implied warranty "would necessarily impose a standard on [Medtronic] different from that imposed by the FDA" and would thus "conflict with the federal requirements already applicable to the device." Pet. App. 67a–68a.

Consequently, the district court granted Medtronic's motion for summary judgment on preemption grounds except insofar as the Riegels alleged that "the Catheter at issue in this action was not manufactured in accordance with the FDA's requirements as set forth in the PMA process," a

claim that the district court held "the MDA does not preempt." Pet. App. 71a. Subsequently, in a December 2, 2003, decision not at issue here, cf. Pet. 12, the district court granted Medtronic summary judgment on both the negligent manufacturing claim and the breach of express warranty claim, finding no factual basis for either claim. Pet. App. 90a.[3] On December 11, 2003, the district court—having found petitioners' claims to be preempted and/or without factual basis—entered judgment for Medtronic. Pet. App. 90a–91a.

The Riegels appealed the district court's preemption ruling to the Second Circuit, which affirmed the grant of summary judgment in its entirety.

The court of appeals began by noting that the PMA process "is lengthy and rigorous." Pet. App. 8a. Not only is the PMA process "'the most stringent'" form of FDA review, but final "'PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).'" Pet. App. 25a (quoting http://www.fda.gov/cdrh/devadvice/pma/). Moreover, the court of appeals noted, "once a device has obtained PMA approval, the manufacturer cannot make any changes that might affect the safety and effectiveness of the device without further FDA approval." Pet. App. 26a. Thus, the court found, upon receiving PMA approval, "the device is clearly subject to the federal device-specific requirement of adhering to the standards contained in its individual, federally approved PMA." *Ibid.*

Turning to petitioners' claims that the trial court had held to be preempted, the Second Circuit observed:

> These claims do not rest on the premise that the particular catheter used during Mr. Riegel's angioplasty deviated from the standards contained in the ap-

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[3] The district court also dismissed Donna Riegel's derivative loss of consortium claim.

> proved PMA application for the Evergreen Balloon Catheter. Rather, the liability-creating premise of all of these claims is that the Evergreen Balloon Catheter itself, in its present PMA-approved form, is in some way defective and therefore requires modification.

Pet. App. 32a. The court of appeals therefore "conclude[d] that the Riegels' claims for strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, and sale would, if successful, impose state requirements that differed from, or added to, the PMA-approved standards for the Evergreen Balloon Catheter." *Ibid.*

Accordingly, the Second Circuit held that petitioners' "strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, and sale claims are preempted by Section 360k(a)." Pet. App. 35a. In so holding, the court of appeals joined what it described as the "growing consensus" that state-law "claims regarding PMA-approved medical devices are * * * preempted." Pet. App. 2a. At the same time, the Second Circuit emphasized that its "preemption analysis is quite limited in scope, affecting the small universe of cases resting on claims alleging liability despite a PMA-approved device's adherence to the standards upon which it secured FDA premarket approval." Pet. App. 3a.

REASONS FOR DENYING THE PETITION

Petitioners assert (Pet. 1–3, 15–18) that review is necessary in this case because of the purported disarray in the lower courts over the interpretation of *Medtronic, Inc.* v. *Lohr*. The Court should deny the current petition, as it denied the petitions filed in *McMullen*, *Knisley*, *Brooks*, *Martin*, and

Kemp, which raised essentially the same issues.[4] As we explain in Part I.A, the lower courts are in significantly less disarray than petitioners suggest. Moreover, in light of the *amicus* brief recently filed by the United States in *Horn*—as well as this Court's decisions in *Buckman* and *Geier*—any lingering disagreement within the lower courts is now likely to disappear. See Part I.B, *infra*. In any event, given the FDA's specific approval of and corresponding requirements for the Evergreen Balloon Catheter, the Second Circuit's decision is plainly correct. See Part II, *infra*.

I. There Is No Reason For This Court To Revisit Its Ruling In *Medtronic, Inc.* v. *Lohr*.

A. Any disagreements among the lower courts are minimal and diminishing.

Petitioners assert that the lower courts are "deeply divided" on the question whether the FDA's approval of a medical device through the PMA process preempts inconsistent state-law damages claims arising from the design, manufacture, and labeling of such devices. Pet. 15–18. Indeed, petitioners assert that there are conflicts as to both whether the PMA process imposes specific federal requirements and whether any duties imposed through state law damages actions can be preempted after *Lohr*. In fact, although a few courts, in outdated opinions, have misinterpreted *Lohr* on each of these issues, the overwhelming weight of authority—including *all* recent authority—favors the Second Circuit's position on each question.

1. On the "federal" side, *Lohr* held that "specific" federal requirements applicable to a device are preemptive under the MDA. See 518 U.S. at 500–501.[5] Based on this Court's

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[4] Three of these prior petitions—the ones filed in *Knisley*, *Martin*, and *Kemp*—were drafted by counsel for petitioners here and were virtually identical to the current petition.

[5] In dissent, four Justices in *Lohr* observed that "[t]he statute makes no mention of a requirement of specificity, and there is no sound basis for

discussion of the "rigorous" nature of the PMA process, and the Court's comparison between the 510(k) process (which "reflect[s] important but entirely generic concerns," *Lohr*, 518 U.S. at 501) and the PMA process (which focuses on "the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements," *ibid.*), the vast majority of courts—and *all* recent decisions—have found that PMA approval and the resultant bar on changes to a FDA-approved device create specific federal requirements that preempt conflicting state common law damages actions. See, *e.g.*, Pet. App. 25a; *McMullen* v. *Medtronic, Inc.*, 421 F.3d 482, 487–488 (7th Cir. 2005); *Cupek* v. *Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005); *Horn*, 376 F.3d at 171–173; *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785, 799 (8th Cir. 2001) (en banc); *Martin* v. *Medtronic, Inc.*, 254 F.3d 573, 585 (5th Cir. 2001); *Kemp*, 231 F.3d at 226–227; *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997); *Worthy* v. *Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998); *Fry* v. *Allergan Med. Optics*, 695 A.2d 511, 516 (R.I. 1997); *Green* v. *Dolsky*, 685 A.2d 110, 117 (Pa. 1996).

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determining that such a restriction on 'any requirement' exists." 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part). We agree; in fact, the history of the FDA regulation relied on by the Court clearly shows that the "specificity" gloss was designed simply to ensure that a counterpart federal requirement *must be in existence* before a state requirement is preempted, not that the federal requirement must be device-specific. See Proposed Rules, *Exemptions From Federal Preemption of State and Local Device Requirements: Proposed Procedures for Consideration of Applications*, 42 Fed. Reg. 30,383 (June 14, 1977). However, the petition does not present this question, because even if specificity is required, the FDA's approval of the Evergreen Balloon Catheter through the PMA process, and the corresponding federal prohibition on any changes to the device's design, manufacturing process or labeling, easily satisfy that requirement.

In contrast to the decisions of the Second, Third, Fifth, Sixth, Seventh, and Eighth Circuits, as well as those of the Pennsylvania, Rhode Island, and Texas Supreme Courts, petitioners can identify (at Pet. 15) decisions of only one federal court of appeals and one state supreme court, cf. S. Ct. R. 10, that did not find PMA approval to be preemptive—*Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), and *Weiland* v. *Telectronics Pacing Systems, Inc.*, 721 N.E.2d 1149 (Ill. 1999). The decisions in these cases, while at odds with the decision below, are old, internally confused, and unlikely to survive even absent this Court's intervention.

For example, the *Goodlin* court found that the PMA process "is clearly specific to the device under review" and that the FDA's Conditions of Approval "constitute specific federal requirements," 167 F.3d at 1376, yet then somehow concluded that the requirements were not "'applicable under [the MDA] to the device,'" *ibid.* (quoting 21 U.S.C. § 360k(a)(1)), and did not establish "a specific requirement that applies to a particular device," *id.* at 1377. The decision is not only internally inconsistent and factually incorrect, but also contrary to *Lohr*. The *Goodlin* court denied preemptive effect to the concededly specific federal requirements, apparently because the FDA's Conditions of Approval were "not promulgated * * * with respect to [a] 'particular device.'" *Ibid.* Yet, so long as the specific federal requirement is applicable to a given device, *Lohr* does not demand that the requirement be applicable *exclusively* to that device. In fact, the FDA has frequently held that federal requirements have preemptive effect even though they apply to a wide array of devices. See, *e.g.*, Final Rule, *Medical Devices*, 45 Fed. Reg. 67,321, 67,322 (Oct. 10, 1980).

Weiland, in contrast, found that no aspect of the PMA process is specific. See 721 N.E.2d at 1152. It based that conclusion on two false premises, however: First, the court held that "[p]remarket approval imposes no ascertainable substantive requirement on the manufacture or design of the

device" (*ibid.*)—a statement that is untrue both in general (see 21 C.F.R. § 814.80 (prohibiting the manufacturer from making any change without FDA authorization to a device that has been approved by the agency through the PMA process if such change would affect the device's safety or effectiveness)) and in this case, where the FDA specifically approved the design, manufacturing process, and labeling of the Evergreen Balloon Catheter (see pages 5–7, *supra*). Second, the court held that the PMA process allows the FDA to assure only "the *minimal* safety of medical devices" (*id.* at 1153 (emphasis added)), a holding inconsistent with *Lohr*, which understood the "reasonable assurance" of safety and effectiveness to be a significant hurdle. *Lohr*, 518 U.S. at 477. In light of *Buckman*'s repetition of the significance of PMA review, see 531 U.S. at 343, the *Weiland* decision is plainly incorrect.[6]

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[6] Petitioners' attempt to conflate the investigational device exemption (IDE) process with the PMA process (see Pet. 16 n.4), in an effort to expand the scope of any conflict, should be rejected. Both of the decisions petitioners cite in footnote 4 are IDE rather than PMA cases and both specifically discuss differences between the PMA process and the IDE process. See *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848, 850 (Mo. 1996) (en banc); *Niehoff* v. *Surgidev Corp.*, 950 S.W.2d 816, 818 (Ky. 1997). As the *Niehoff* court explained, the IDE process is designed "to encourage research and development" (950 S.W.2d at 818), whereas the PMA process includes "a determination that the product is safe and effective" (*ibid.*). Even were a state requirement not to be preempted based on the IDE process, then, the FDA's careful determination at the PMA stage that a product is safe and effective in light of all known risks should still preempt conflicting state requirements, including requirements imposed through common law tort actions. See *Lohr*, 518 U.S. at 501 ("The generality of [requirements imposed under the 510(k) process] make this quite unlike a case in which the Federal Government *has weighed the competing interests relevant to the particular requirement in question*, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.") (emphasis added).

In the seven years since they were decided, no other court of appeals and no other state supreme court has joined either the Eleventh Circuit's decision in *Goodlin* or the Illinois Supreme Court's decision in *Weiland*. Given their internal flaws, this Court's reminder that the PMA process subjects a device to "thorough review," *Buckman*, 531 U.S. at 344, and the FDA's recent declaration that "through the PMA approval process [the FDA] certainly establishes 'specific requirements' applicable to a 'particular device,'" Brief for United States as *Amicus Curiae* (*Horn Amicus* Br.), 2004 WL 1143720, at *16, filed in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (see also pages 19–22, *infra*), there is no reason to believe that any court will repeat the errors in *Goodlin* or *Weiland*.

2. On the "state" side of the *Lohr* preemption equation, petitioners assert (Pet. 16) that there is a "profound" split of authority over whether state law damages claims can ever be preempted by divergent federal requirements. In fact, the vast majority of lower courts, and *all* courts to have considered the issue recently, have held that such claims can be preempted,[7] a decision that is plainly correct under *Lohr* (see pages 26–28, *infra*). Only one federal court of appeals or state court of last resort, cf. S. Ct. R. 10, has relied on a contrary finding to limit the preemptive scope of the MDA—the Tenth Circuit in *Oja* v. *Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997).[8] *Oja* is one of the earliest appellate deci-

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[7] See, *e.g.*, Pet. App. 30a; *McMullen*, 421 F.3d at 487; *Cupek*, 405 F.3d at 424; *Horn*, 376 F.3d at 173–177; *Brooks*, 273 F.3d at 799; *Martin*, 254 F.3d at 584; *Kemp*, 231 F.3d at 224; *Mitchell*, 126 F.3d at 913–914; *Papike* v. *Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997); *Worthy*, 967 S.W.2d at 376–377; *Fry*, 695 A.2d at 517; *Green*, 685 A.2d at 117–118.

[8] Neither *Niehoff* nor *State ex rel. Miller* v. *New Womyn, Inc.*, 679 N.W.2d 593 (Iowa 2004), the only state supreme court decisions cited by petitioners (Pet. 17), holds that state common law claims are not subject to preemption when a medical device has received FDA approval through the PMA process. Petitioners' parenthetical quotation suggesting that the

sions to interpret *Lohr*, did not involve a device that had been approved through the PMA process, and plainly misinterprets *Lohr* in a variety of ways.

For example, the Tenth Circuit never directly considered whether a finding of liability under a state common law duty would "have the effect of establishing a substantive requirement of a specific device"—even though the court earlier had acknowledged that such an inquiry was necessary. 111 F.3d at 788 (quoting *Lohr*, 518 U.S. at 500 (in turn quoting 21 C.F.R. § 808.1(d)(1)) (internal quotation marks omitted). More importantly, the court failed to appreciate that a majority of this Court had expressly held in *Lohr* that state common law damages actions impose "requirements" that can be preempted by federal requirements. See pages 26–27 & n.15, *infra*.[9]

Supreme Court of Kentucky, in *Niehoff*, held that state law damages claims are not specific requirements is taken out of context and misread. Rather, the *Niehoff* court held that the IDE process (not the PMA process) imposes no specific *federal* requirement against which to compare Kentucky's common law damages claims. See 950 S.W.2d at 822 ("[t]he claim * * * of preemption to the defective design allegation fails because there is no specific federal requirement"). As discussed above (at page 15 n.6), the *Niehoff* court also focused on the significant differences between the PMA process and the IDE process. In *New Womyn*, a case brought by the state attorney general under the state's consumer fraud statute, the device at issue had not been approved by the FDA at all, let alone after "running the gauntlet of the PMA process." *Lohr*, 518 U.S. at 494. Indeed, an FDA "employee with extensive experience in the review of applications regarding new medical devices" testified that a device similar to that at issue in *New Womyn* "was on display in the public lobby of the FDA building in a collection of what the FDA labeled 'quack devices.'" *New Womyn*, 679 N.W.2d at 597. Thus, even if the Supreme Court of Iowa had discussed whether a state law damages claim could in theory be preempted (which it did not), there was no specific federal requirement in *New Womyn* to preempt any state law claim.

[9] The *Oja* court was confused not only about what state requirements may be preempted but also about what federal requirements are preemptive. Thus, though the court was confronted with a claim (for failure to

This single aberrant decision by a federal court of appeals, rendered shortly after *Lohr*, does not warrant this Court's attention. In the nine years since *Oja*, there has been no movement by any other court toward that court's erroneous analysis. Moreover, given this Court's holding in *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005), that the term "requirements" in the identically-worded FIFRA includes common law claims, the unanimous view of the other courts of appeals that such claims may be preempted, and the United States' similar view as expressed in its *amicus* brief in *Horn* (see pages 21–23, *infra*), there is no reason to believe that the Tenth Circuit would continue to follow *Oja* after further analysis of this Court's holding in *Lohr*.

* * * * *

Petitioners, who suggest that review is warranted in this case because *Goodlin*, *Weiland*, and *Oja* "remain the law in those jurisdictions," summarily dismiss the prospect that "the courts that found no preemption might change their minds or be overturned en banc." Pet. 2–3. Petitioners' pessimism, however, is unwarranted. The issue of preemption in the PMA context arises relatively infrequently.[10] Thus, the courts

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warn) arising from a device approved, at the time it was implanted, only through the 510(k) process (see 111 F.3d at 787 n.2), it held that the FDA's 510(k) review led to specific federal requirements—despite this Court's contrary holding in *Lohr*. See 111 F.3d at 789.

[10] As the Second Circuit noted below, last year "approximately ninety-nine percent of [Class III] devices went through the § 510(k) process and only *one percent* went through the PMA process." Pet. App. 13a (emphasis in original). See also *Lohr*, 518 U.S. at 479 ("the § 510(k) premarket notification process became the means by which most new medical devices—including Class III devices—were approved for the market"). Because "the vast majority of Class III medical devices" enter the market via the § 510(k) process (Pet. App. 12a), and because the § 510(k) process is in essence a grandfathering provision that allows devices "substantially equivalent" to pre-MDA devices to enter the market without PMA approval (*ibid.*), it is not surprising that PMA-based preemption claims did not arise immediately after passage of the MDA. The first opportunity to assert preemption based on PMA approval would not have arisen until

that issued those early, anomalous decisions have had no opportunity to revisit their holdings.[11] Given the fact that no federal court of appeals and no state supreme court has followed—and, indeed, each such court has specifically *rejected*—those decisions in the years since they were issued, it is highly unlikely that they will be reaffirmed when the opportunity arises. On the contrary, given this Court's subsequent guidance in *Geier*, *Buckman*, and *Bates*, and the FDA's authoritative declaration in *Horn*, any vestigial conflict that still exists will almost certainly disappear without intervention by this Court.

B. The lower courts should be allowed to consider the implications of the FDA's *amicus* brief in *Horn*.

In *Lohr*, this Court recognized that "Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect." 518 U.S. at 495–496. The Court further recognized that, as the federal agency to which Congress has delegated the authority to implement the MDA, the FDA "is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,'

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after a device had both "run[] the gauntlet of the PMA process," 518 U.S. at 494—a process that may take many years, see, *e.g.*, *Kemp*, 231 F.3d at 219 (regulatory review culminating in PMA approval lasted eight years)—*and* had allegedly caused injury to a patient. Therefore, contrary to petitioners' suggestion (Pet. 23), the fact that no court addressed PMA-based preemption in the years immediately following enactment of the MDA in no way undermines the fact that § 360k(a) clearly preempts state law claims that would impose requirements "different from" or "in addition to" the federal requirements embodied in the FDA's pre-market approval of their devices.

[11] A thorough review of the Westlaw Keycite database performed on October 3, 2006, reveals that no Tenth Circuit case citing *Oja*, no Eleventh Circuit case citing *Goodlin*, and no Illinois Supreme Court (or even appellate court) case citing *Weiland* has concerned common law damages claims in connection with a PMA-approved device.

and, therefore, whether it should be pre-empted." *Id.* at 496 (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). Given "the ambiguity in the statute" and "the congressional grant of authority to the agency on the matter contained within it," the Court found it appropriate to "giv[e] substantial weight to the agency's view of the statute." *Ibid.*

The FDA has recently provided authoritative guidance on the scope of § 360k's preemptive effect in the PMA context. At the request of the Third Circuit, the United States submitted an *amicus* brief on behalf of the FDA in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (2004). The FDA's *amicus* brief explains at length and in detail why "FDA pre-market approval for a new medical device preempts state law tort judgments." *Horn Amicus* Br., 2004 WL 1143720, at *2.

With respect to the federal side of the equation, the FDA stated unequivocally that "through the PMA approval process [the FDA] certainly establishes 'specific requirements' applicable to a 'particular device.'" *Id.* at *16. The FDA noted that "[a]lthough the PMA approval order does not itself expressly reiterate all of the specific features the device's design, labeling, and manufacturing processes must have, it specifically approves as a matter of federal law those features as set forth in the application and binds the manufacturer to produce and market the product in compliance with the specifications as approved by [the] FDA." *Id.* at *24.

With respect to the state side of the preemption equation, the FDA endorsed the view—subscribed to by a majority of the Justices in *Lohr*—that "state tort law judgments do impose a requirement for purposes of preemption under the MDA when a common law action 'would impose a requirement different from, or in addition to, that applicable under the FDCA.'" *Id.* at *18 (quoting *Lohr*, 518 U.S. at 511 (O'Connor, J., concurring in part and dissenting in part)). The FDA observed that, absent an allegation that the device in question deviated from the requirements imposed by the FDA through the PMA process, "any finding of liability

* * * would necessarily rest upon an implicit requirement that [the] device be designed, manufactured, or marketed in a way that differs from the way approved by [the] FDA." *Ibid.*

The FDA also emphasized in its brief the "very strong public policy considerations" that support finding PMA approval preemptive of state common law claims. *Id.* at *25. According to the FDA—the agency charged with implementing the MDA—"[s]tate common law tort actions threaten the statutory framework for the regulation of medical devices." *Ibid.* As the agency explained, during the PMA process it conducts "a thorough review of a substantial scientific record" (*id.* at *16) and performs a "careful balancing" of the benefits and risks associated with a particular device (*id.* at *29). State tort actions, however, usurp "the central role of [the] FDA" by requiring "lay judges and juries to second-guess the balancing of benefits and risks of a specific device." *Id.* at *25. Because such second-guessing "may disrupt the careful balancing performed by the FDA in the PMA process" (*id.* at *29), state common law claims such as those asserted in *Horn*—and here—"are preempted under federal law." *Id.* at *31.

Given the agency's "unique role in determining the scope of § 360k's pre-emptive effect" (*Lohr*, 518 U.S. at 495–496), the FDA's clear guidance in *Horn* further demonstrates that there is no need for this Court to grant review in this case. The FDA's "reasoned analysis" (*Horn Amicus* Br., 2004 WL 1143720, at *30) is entitled to substantial weight as "the agency's fair and considered judgment on the matter in question." *Auer* v. *Robbins*, 519 U.S. 452, 462 (1997) (deferring to agency interpretation of ambiguous regulation contained in *amicus* brief submitted in dispute between private parties). This is especially true when coupled with this Court's renewed recognition of "the PMA review's rigor" (*Buckman*, 531 U.S. at 348), and Justice Stevens' reminder that "in *Medtronic, Inc.* v. *Lohr*, [this Court] recognized that the statutory reference to 'any requirement' imposed by a

State * * * may include common-law duties" (*Geier*, 529 U.S. at 897 (Stevens, J., dissenting); see also n.15, *infra*).

There is simply no reason to believe that those few courts that misinterpreted *Lohr* soon after it was decided will not now take heed of the FDA's *amicus* brief in *Horn* and join the clear consensus finding state common law claims that would impose requirements that are "different from" or "in addition to" the federal requirements embodied in the FDA's pre-market approval of a device to be preempted by federal law.[12] In the unlikely event that those courts, upon reconsideration, choose to adhere to their prior decisions, the Court can grant review at that time.

II. The Decision Below, Finding Preemption Of State Law Claims Based On The Requirements Imposed By The PMA Process, Is Plainly Correct.

Review is also unwarranted because the decision below is consistent with *Lohr*, with Congress's intent in passing the MDA, with the views of the FDA, and with common sense. Section 360k(a) prohibits any state "requirement" that is "different from, or in addition to, any requirement applicable under [the MDA] to the device" and "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." Thus, for preemption to occur, there must be a federal re-

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[12] Notably, each circuit to have considered the question since the filing of the FDA's *amicus* brief in *Horn* has embraced the government's view that PMA approval preempts state common-law claims that would impose requirements "different from, or in addition to" the requirements imposed through the PMA process. See, *e.g.*, Pet. App. 37a–38a; *Horn*, 376 F.3d at 177. Petitioners do not cite, and respondent is not aware of, any district court or state court decision to arrive at a contrary conclusion since the filing of the FDA's *amicus* brief in *Horn*. Cf. *Hughes* v. *Cook*, No. 2:06-CV-02027, slip op. at 13 (W.D. Tenn. Sept. 27, 2006) (holding state common-law claims to be preempted by PMA approval based on *Kemp*, which, the court explained, "is heavily reenforced by the FDA's *amicus curiae* brief submitted in *Horn*").

quirement, a state requirement, and some "differen[ce]" between the two. See 518 U.S. at 500. These criteria are easily satisfied here.

1. The Second Circuit correctly held that FDA approval of a medical device through the PMA process can create federal requirements applicable to the device that would preempt conflicting state requirements. Although the Court in *Lohr* did not directly reach that question, both the majority and the dissenting opinions are fully consistent with a finding that the PMA process can impose preemptive federal requirements. See 518 U.S. at 501 (discussing preemption where "the Federal Government has weighed the competing interests relevant to the particular requirement in question," in contrast to the 510(k) process); *id.* at 512 (O'Connor, J., concurring in part and dissenting in part) (disputing requirement that federal requirements need to be specific). Moreover, the decision below is entirely consistent with the views of the FDA, which has declared that the PMA process "establishes 'specific requirements' applicable to a 'particular device.'" *Horn Amicus* Br., 2004 WL 1143720, at *16.[13]

It is clear that the PMA process in fact established specific requirements applicable in particular to the Evergreen Balloon Catheter. During that process, Medtronic submitted "test data, the results of clinical investigations and design information" as well as details of the device's manufacturing

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[13] The FDA's view is well supported by statute. Many provisions of the MDA refer to "requirements" imposed by the FDA through the PMA process (pursuant to 21 U.S.C. § 360e). See 21 U.S.C. §§ 331(e), 351(f)(1)(A)(i), 360(k)(2), 360c(b)(1)(A), 360c(c)(2)(A), 360c(e)(1)(B), 360e(b), 360e(c)(2), 360e(d)(2)(C), 360e(f), 360j(a), 360j(m)(2), 382(a)(2)(A). Under federal law, moreover, a device that is approved for marketing through the PMA process cannot be "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80; see also *id.* § 814.39. Put differently, the manufacturer is *required* to follow the design and other specifications embodied in the PMA application and approved by the FDA.

process and "full copies of proposed product labels." Pet. App. 65a–67a. After a "rigorous review" of this information, all of which "was specific to the Evergreen Balloon Catheter," the FDA "explicitly approved" the device's design, manufacturing method, and labeling. Pet. App. 28a, 65a–67a. Because Medtronic was thereafter prohibited from making any changes that might affect the safety or efficacy of the Evergreen Balloon Catheter, "the device is clearly subject to the federal, device-specific requirement of adhering to the standards contained in its individual, federally approved PMA." Pet. App. 26a. See also *Kemp*, 231 F.3d at 226–227 ("'PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling' and is 'specific to the product.'") (quoting *Mitchell*, 126 F.3d at 913).[14]

Significantly, approval through the PMA process entailed a finding, based on the FDA's painstaking review of an immense amount of scientific data, that "the device is both

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[14] Petitioners assert (Pet. 20) that "the PMA process itself does not impose specific federal 'requirements' * * * because the device's specifications originate with the manufacturer, not the FDA." Petitioners are wrong. Once the PMA application has been approved, often after prolonged discussions and agency-directed modifications, the device's manufacturer is legally obligated to adhere to the specifications set forth in the application and may not change them without FDA approval. See 21 C.F.R. § 814.80; see also *Horn*, 376 F.3d at 171–172. Moreover, the case that petitioners cite, *American Airlines, Inc.* v. *Wolens*, 513 U.S. 219, 228–229 (1995), does not suggest otherwise. In that case, this Court held that the Airline Deregulation Act preempted certain claims but did not preempt a breach of contract claim based on the defendant's "self-imposed undertakings." In so holding, however, the Court specifically noted that the defendant's contractual duties were "privately ordered obligations"; furthermore, there was no dispute that the defendant in that case could have unilaterally revised its self-imposed duties on a prospective basis without obtaining regulatory approval. *Id.* Here, by contrast, Medtronic could not—either unilaterally or in agreement with petitioners—alter its obligations after receiving PMA approval without first obtaining the FDA's consent.

safe and effective." *Lohr*, 518 U.S. at 477 (citing 21 U.S.C. § 360e(d)(2)). See also Pet. App. 25a ("'PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).'"); *Horn Amicus* Br., 2004 WL 1143720, at *16 ("The approval perforce embodies the agency's conclusion that there is a 'reasonable assurance of safety and effectiveness' of the device."). The determination that a product is safe and effective, made after weighing "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use" (21 U.S.C. § 360c(a)(2)(C))—in a process characterized by this Court as "running the gauntlet" (*Lohr*, 518 U.S. at 494) and "exhaustive" (*Buckman*, 531 U.S. at 349)—is of necessity the determination that the attributes of that device are an appropriate compromise that should not be modified by state law. See *Horn Amicus* Br., 2004 WL 1143720, at *29 ("state co-regulation" through tort actions "may disrupt the careful balancing performed by [the] FDA in the PMA process").

The regulatory history confirms this point. Petitioners rely on 21 C.F.R. § 808.1(d), cf. Pet. 15, but—as evidenced by the FDA's *amicus* brief in *Horn*—that regulation is entirely consistent with holding that the PMA process establishes device-specific requirements. Section 808.1(d) explains that state or local requirements will be preempted when the FDA "has established specific counterpart regulations *or there are other specific requirements applicable to a particular device under the [MDA]*." (emphasis added). The preamble to section 808.1(d) notes that a state cannot, through its own premarket approval process, establish requirements inconsistent with the FDA's premarket approval process, and further explains:

> For a device classified in class III under section 513(d) of the act, the counterpart FDA requirement is established on the date the device can not lawfully

> be marketed without application for premarket approval. * * * Once these FDA requirements are established, different or additional State requirements are preempted.

Final Rule, *Exemptions From Federal Preemption of State and Local Device Requirements: Procedures For Consideration of Applications*, 43 Fed. Reg. 18,661, 18,664 (May 2, 1978) (emphasis added).

Finally, Congress viewed the PMA process as imposing "requirements" that would trigger preemption. For example, prior to passage of the MDA, California's "Sherman Food, Drug, and Cosmetic Law" required pre-market approval of all new devices sold in the state. Congress specifically referred to this requirement as one that the FDA should allow to continue by expressly exempting it (under 21 U.S.C. § 360k(b)) from preemption by the PMA process. See H.R. REP. NO. 94-853, at 45–46. No such exemption would have been thought necessary if the PMA process did not establish requirements otherwise preemptive of the state law.

2. The Second Circuit also correctly found that petitioners' state law claims, to the extent those claims were based on a showing that the device should have been manufactured, designed, or labeled in a manner different from that required by the PMA, were preempted under § 360k. A majority of this Court held in *Lohr* that "the MDA will sometimes preempt a state-law tort suit" (518 U.S. at 503 (Breyer, J., concurring)), because "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action" (*id.* at 504–505); accord *id.* at 509 ("state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA.") (O'Connor, J., concurring in part and dissenting in

part).[15] When a state law tort action is based on a requirement that is not identical to a federal requirement, that claim would seem definitionally to be "different from, or in addition to" (21 U.S.C. § 360k(a)(1)) the federal requirement. Indeed, as noted by the FDA, "any finding of liability * * * would necessarily rest upon an implicit requirement that [the] device be designed, manufactured, or marketed in a way that differs from the way approved by [the] FDA." *Horn Amicus* Br., 2004 WL 1143720, at *18.

Here, the PMA process imposed specific requirements on Medtronic, including the requirement to label the Evergreen Balloon Catheter in precisely the manner approved in its PMA application, with, for example, warnings that the device not be used in patients with calcified stenoses and not be inflated to more than the Rated Burst Pressure. See pages 7–8, *supra*. The district court found that petitioners had prof-

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[15] Indeed, contrary to what petitioners suggest (Pet. 20–21), *all* members of the *Lohr* Court agreed that state common-law claims could potentially be preempted under the MDA. Thus, in Section V of the *Lohr* decision, the Court, referring to § 360k(a) and 21 C.F.R. 808.1(d), observed that "we do not believe that this statutory and regulatory language necessarily precludes . . . 'general' state requirements from ever being preempted." 518 U.S. at 500. Significantly, Justice Stevens, who wrote the opinion in *Lohr*, has himself stated that *Lohr* "recognized that the statutory reference to 'any requirement' imposed by a State * * * may include common-law duties." *Geier*, 529 U.S. at 897 (Stevens, J., dissenting). See also *Geier*, 529 U.S. at 867 (noting that "a majority of this Court" in *Lohr* recognized that state tort actions may be preempted as imposing conflicting "requirements"); cf. *Bates*, 544 U.S. at 443 ("the term 'requirements' * * * reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties"). Because the entire *Lohr* Court agreed that state common-law claims could, at least potentially, be preempted, the fact that Justice Breyer's articulation of this proposition is contained in a concurrence is beside the point. Cf. Pet. 21. The *Lohr* Court was not divided over the question *whether* state common-law claims might be preempted; the Justices disagreed only over the *frequency* with which they would be preempted. See 518 U.S. at 502–503 (Stevens, J., plurality); *id.* at 508 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., dissenting).

fered no evidence suggesting that Medtronic had deviated from the requirements imposed by the FDA through the PMA process. Pet. App. 90a. Thus, were a jury to impose liability on Medtronic under state law, that jury would of necessity be imposing a requirement "different from" or "in addition to" that imposed by the FDA under federal law.

3. Putting aside the legalisms of *Lohr*, petitioners' position cannot possibly be consistent with Congress's decision to enact the MDA and to make that statute preemptive. The MDA strikes a careful balance between shielding the public "against unsafe, unproven, ineffective, and experimental medical devices" and ensuring that progress in the development of medical devices is not "stifle[d]" by "excessive or ill-conceived" regulation. H.R. REP. NO. 94-853, at 10; see also *FDA Oversight: Medical Devices: Hrg. Before the Subcomm. on Oversight & Investigations of House Comm. on Energy & Commerce*, 97th Cong., 2d Sess. 5 (1982). A key element in striking this balance is Congress's delegation of exclusive authority to the FDA. Permitting state review and nullification of the FDA's PMA decisions would run roughshod over this carefully calibrated enforcement scheme and would impose the "undu[e] burden[]" of differing state regulation that Congress aimed to avoid by including in the MDA a "general prohibition on non-Federal regulation." H.R. REP. NO. 94-853, at 45.

Moreover, petitioners raise a red herring when they assert that "the decision below leaves patients injured by the most risky devices with no remedy." Pet. 22. As the Second Circuit itself emphasized, the scope of its decision is "quite limited." Pet. App. 36a. First, it affects only those devices that the FDA deems safe and effective after rigorous PMA review; it does not apply to the vast majority of Class III devices, 99% of which enter the market via the less-exacting 510(k) process. Second, the decision "does not even hold that all state tort claims as to PMA-approved devices are preempted." *Ibid.*

> On the contrary, * * * tort claims that are premised on a manufacturer's deviation from the standards set forth in the device's approved PMA application—such as the Riegel's negligent manufacturing claim—are in no way preempted. Only those claims that allege liability despite a PMA-approved device's adherence to those standards are, pursuant to this decision, preempted. As one article recently noted, "[t]his is a relatively small universe of cases."

Ibid. (quoting Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval Under the Medical Device Amendments*, 59 FOOD DRUG L.J. 245, 263–264 (2004)). See also *Lohr*, 518 U.S. at 495 ("Nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."); *Mitchell*, 126 F.3d at 914 ("to the degree that these claims may be read to allege that [the device manufacturer] failed to meet the standards set forth in the PMA process, the allegations are not preempted"). Thus, contrary to petitioners' assertion, patients remain fully protected, both by the FDA's rigorous scrutiny of PMA-approved devices and by the ability to enforce FDA-imposed requirements through common law claims.

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In the final analysis, petitioners present this Court little evidence of a significant split in authority below; what inconsistencies there may be in the interpretation of *Lohr* are likely to be resolved in light of the FDA's *amicus* brief in *Horn* and through further litigation in the lower courts. Petitioners provide no good reason why the Court, having repeatedly declined to review this issue, should grant review here, or why the issue deserves the Court's attention at the present time.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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